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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,162	03/08/2001	Robert Getts	4081.005	6213

7590 06/19/2002

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EXAMINER
CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
1637	5

DATE MAILED: 06/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/802,162	Applicant(s) GETTS, ROBERT	
	Examiner Suryaprabha Chunduru	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

1. Claims 1-19 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

a. Claims 1-19 are indefinite over the recitation of "capable of emitting" because capability is a latent characteristic and the claims do not set forth the criteria by which to determine capability. That is, it is not clear whether the recited probes have the potential to emit or do in fact does emit the detectable signal. Amendment of the claim to read, for example, "which emits"

would obviate this rejection.

b. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is incomplete and indefinite because Claim 1 recites 'plurality of features' which makes the claim indefinite because it is not clear what the term accomplishes for. Amendment to clearly recite the term would obviate the rejection.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7-8, 10-11, 13, and 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Nilsen et al. (USPN. 5,487,973).

Nilsen et al. teach a method for detecting a specific nucleic acid in a target sample wherein Nilsen et al. teach that the method comprises (i) contacting a microarray having specific probe sequences with a mixture containing a first component comprising labeled target nucleic acid (DNA or RNA) having a capture sequence and a second component comprising a dendrimer having at least one arm with a nucleotide sequence complementary to the capture sequence of the first component (see column 14, lines 30-35, column 15, lines 37-63); (ii) mixing the first and second components at a temparature to form a bridge between the two components to enable the cross-linking of first component to the second (see column 16, lines 8-11); and incubating the bound mixture with the said microarray and detecting signal as an indication of the binding of the target sequence to the specific probe sequence on the microarray (see column 16, lines 12-67, column 18, lines 27-51). Nilsen et al. also teach that the method comprises annealing times ranging from 8minutes (see column 20, lines 24-44) to overnight to 2-6 weeks (see column 3, lines 49-60); detection of hybridization pattern includes detecting the detectable signal (see column 20, lines 38-40); the method comprises hybridization buffer (see column 19, lines 14-26); the unbound dendrimers were removed by a washing step (see column20, lines 35-37); and the isolation of nucleic acid includes spin column (see column20, lines 17-19). Thus the disclosure of Nilsen et al. meets the limitations in the instant claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-6, 9, 12, 14-17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nilsen et al. (USPN. 5,487,973). And in view of Wang (6,004,755).

Nilsen et al. teach a method for detecting a specific nucleic acid in a target sample wherein Nilsen et al. teach that the method comprises (i) contacting a microarray having specific probe sequences with a mixture containing a first component comprising labeled target nucleic acid (DNA or RNA) having a capture sequence and a second component comprising a dendrimer having at least one arm with a nucleotide sequence complementary to the capture sequence of the first component (see column 14, lines 30-35, column 15, lines 37-63); (ii) mixing the first and second components at a temparature to form a bridge between the two components to enable the cross-linking of first component to the second (see column 16, lines 8-11); and incubating the bound mixture with the said microarray and detecting signal as an indication of the binding of the target sequence to the specific probe sequence on the microarray (see column 16, lines 12-67, column 18, lines 27-51). Nilsen et al. also teach that the method comprises annealing times ranging from 8minutes (see column 20, lines 24-44) to overnight to 2-6 weeks (see column 3, lines 49-60); detection of hybridization pattern includes detecting the detectable signal (see column 20, lines 38-40); the method comprises hybridization buffer (see column 19, lines 14-26); the unbound dendrimers were removed by a washing step (see column20, lines 35-37); and the isolation of nucleic acid includes spin column (see column20, lines 17-19). However, Nilsen et al. did not teach end-labeling or attaching capture sequence to the target sample. Though

Nilsen et al. disclose hybridization buffer and conditions for hybridization assay, Nilsen et al. did not teach specific hybridization buffer composition, conditions for hybridization.

Wang teaches a method for quantitative gene expression analysis using microarray, wherein Wang teaches end-labeling of target nucleic acid (mRNA) in the presence of labeled oligo (dT) primer, reverse transcriptase under conditions sufficient for initiating reverse transcription of said mRNA in to cDNA (see column 5, lines 3-39). Further, Wang also teaches (i) gel purification of labeled target (see column 9, lines 20-21); hybridization wash solutions including varying concentrations of SSC and SDS, hybridization conditions including hybridization temperatures ranging from 40^0 - 60^0 C and hybridization chamber. (see column 10, lines 25-63).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify a method for detecting a nucleic acid sequence as taught by Nilsen et al. with a method for quantitative gene expression using end-labeling and hybridization as taught by Wang to achieve expected advantage of developing a method for enhanced sensitivity of detecting a target nucleic acid because Nilsen et al. states that "there is a need for standardization of detection methods to overcome or minimize the drawbacks of currently used methods to provide a versatile, rapid and to eliminate false positives or noise problems" (see column 2, lines 42-56). One alternative favoring standardization, expressly motivated by Wang is to use end labeling of target nucleic acid and hybridization conditions.

Further selection of specific hybridization buffers, hybridization conditions and automation of hybridization assay represents routine optimization with regard to hybridization, which routine optimization parameters are explicitly recognized in Wang. As noted in *In re*

Aller, 105 USPQ 233 at 235, more particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to is cover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the hybridization buffers or conditions performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art. An ordinary practitioner would have been motivated to combine the method of Nilsen et al. with the method of Wang in order to achieve the expected advantage of developing a sensitive method for detecting a target nucleic acid.

No claims are allowable.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru

June 5, 2002

JEFFREY FREDMAN
PRIMARY EXAMINER